K040718

APR - 2 2004

510(k) Summary

February 5, 2004

Submitter:
DHD Healthcare Corporation
One Madison Street
Wampsville, NY 13163

Contact: David Geary, Regulatory Affairs Manager
Phone: 315-363-2330 x267
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Device Name:

Product Code Name:	TRUST
Trade name:	To Be Determined
Common Name:	Nebulizer
Classification Name:	Nebulizer – 868.5630

Predicate Devices:
Hope Nebulizer
K980407
B&B Medical Technologies
P.O. Box 1958
Loomis, CA 95650

Device Description:
The DHD TRUST is indicated for use as a single patient use nebulizer. TRUST is a small plastic device that threads onto a regulated flow meter supplying air or oxygen. A reservoir bottle threads to the bottom of TRUST to hold water and/or medication. Trust has a secondary port on the side of the device to allow for supplemental air, oxygen, or heliox.

Intended Use:
TRUST is intended for use as a nebulizer.

Technological Characteristics Compared to Predicate:
Hope and TRUST use identical technology.

Summary of Studies:
Testing of particle size delivery was performed in accordance with the guidance document "REVIEWER GUIDANCE FOR NEBULIZERS, METERED DOSE INHALERS, SPACERS AND ACTUATORS". The results of this testing shows particle size delivery to be equivalent between TRUST and the predicate.

Conclusion Drawn from Studies
For the indications for use, the DHD TRUST nebulizer performs substantially equivalent to the predicate device, B&B Medical Technologies' Hope nebulizer. In

the opinion of DHD, it is substantially equivalent to the predicate device and does not adversely affect safety and effectiveness compared to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 2 2004

DHD Healthcare Corporation
C/O Mr. Robert Mosenkis
Citech
5200 Butler Pike
Plymouth Meeting, PA 19462-1298

Re: K040718
Trade/Device Name: Trust
Regulation Number: 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: March 18, 2004
Received: March 19, 2004

Dear Mr. Mosenkis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-5613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

for Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if known): K040718

Device Name: TRUST

1 – Intended Use:

The DHD TRUST is intended for use as a nebulizer.

2 - Indications:

- The DHD TRUST provides additional hydration to help loosen secretions for patients whom extended therapy is required.
- The DHD TRUST delivers aerosolized medications and diagnostic formulations.

3 - Target Patient Population

Patients with asthma, pneumonia, COPD, or any other condition in which appropriate medications would be nebulized.

4 - Intended Environment For Use

To be used under medical supervision in hospitals, nursing homes, extended care facilities and outpatient clinics.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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